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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/018,484	05/10/2002	Rochus Jonas	MERCK 2333	8097

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EXAMINER

FORD, JOHN M

ART UNIT PAPER NUMBER

1624

DATE MAILED: 11/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No. <u>10/018484</u>	Applicant(s) <u>Ro chus et al</u>	
Examiner <u>J. M. Ford</u>	Group Art Unit <u>1604</u>	

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE THREE MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

**Status**

- ☐ Responsive to communication(s) filed on \_\_\_\_\_
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

**Disposition of Claims**

- ☒ Claim(s) 1-9 is/are pending in the application.
- ☐ Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- ☒ Claim(s) 1-9 is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☐ Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

**Application Papers**

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119 (a)-(d)**

- ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☒ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been received.
- ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_
- ☒ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

**Attachment(s)**

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_
- ☐ Interview Summary, PTO-413
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other \_\_\_\_\_

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The claims in the application are claims 1—9.

The plural 's' on compounds of the formula, throughout, make the claims read on mixtures, rather than one at a time compound.

Claiming is alternative. One at a time compound.

A compound selected from the group consisting of the compounds of formula I – is suggested.

Mixtures are an entire other invention.

See Ex parte Tinsley, U.S. Patent file 3,311,643, Paper # 20, page 3 of 5 page Decision. 35 U.S.C. 112, 2<sup>nd</sup> paragraph.

Compounds of the type claimed here are classified as heterocyclic in classes 544. Mixtures are in class 252.

The last line of clams 1 and 2 should be "or" salts thereof, not "and" salts.

This is a 371 application. Content in 371 applications is controlled by 37 CFR 1.475. Rule 475 makes it clear that once a compound claim is determined to have allowable language that applicants are entitled to have, at most, one use of those compounds and one method of making those compounds; provided the claims are all of the same scope.

Claim 3 is directed to two processes. Claim 3 should be re-written to one process, or cancelled.

Claims 6—9 are not "statutory", as they claim in terms of "use", and as a "medicament". A "medicament" is not statutory. The claim has to be expressed

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as a Pharmaceutical composition, or a method of treating a ~~Real~~ <sup>Real World</sup> Disease.

All "potency disorders" is too vague.

The recent utility guidelines set by PTO require applicant to meet the requirements as stated in Brenner v. Manson in, 148 USPQ 689, which requires that utility be developed to a point where "specific benefits exist in currently available ~~from~~ <sup>to</sup>". Similar, is the "immediate benefit to the public" standard that Nelson v. Bowler, 206 USPQ 880 refers to. The standard set forth in the concurring opinion of In re Hartop, 135 USPQ 419 is "whether the invention has been brought to such perfection as to be capable of practice/employment". This language is echoed in Bindra vs. Kelly, 206 USPQ 570.

The PTO has amended the guidelines to clarify "specific utility". The court focused on the fact that the applicants failed <sup>to</sup> identify a "specific utility" in Brenner v. Manson. Claim 7 is not expressed in terms of treating a specific disease.

Patents are issued by the Commerce Department to stimulate Commerce. The Court reasoned that the utility should relate to the real world of Commerce that would be understandable; not a laboratory curiosity or a broad assay for many possible diseases.

This requirement of one specific utility is consistent with Unity of Invention Practice in International Application and National Phase Applications under 35 U.S.C. 371, <sup>in 37 CFR 1.475</sup> and PCT Rule 13.2 for PCT applications.

Therefore, applicants should direct the method claims to a "specific utility".

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Claims 8 and 9 violate 35 U.S.C. 112, since they are drafted in terms of use. See *Clinical Product vs. Brenner*, 255 F. Supp. 151; 149 USPQ 475 (D.C. District Columbia 1966).

Claim 5 should read: A pharmaceutical composition comprising<sup>a</sup>/compound of claim 1 in admixture with an inert carrier.

A method should read: A method of treating (blank) comprising administering an effective amount of a compound of claim 1 to a person in need of such treatment.

Any claim not specifically rejected, is rejected for the reasons from which it depends is rejected.

No dependent claim could be allowed, as it would have to read back through rejected words and terms of the claim from which it is dependent. None of the claims comply with 35 U.S.C. 112, 2<sup>nd</sup> paragraph.

No 1449 ~~from~~ is found to acknowledge consideration of the prior art.

Claims 4 and 8 are rejected under 35 U.S.C. 103. The <sup>actual</sup> formation of a composition by bringing into contact the active ingredient with an inert carrier is old since the time of Alchemists work<sup>ing</sup> in caves.

Claim 3 is rejected under 35 U.S.C. 112, 2<sup>nd</sup> paragraph as "converted" does not describe a process.

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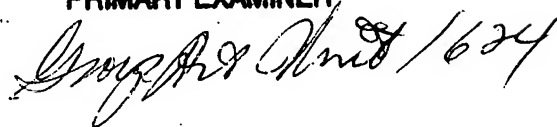
Claim 6 et seq. Need<sub>3</sub> to be limited to one use. It is not believable, on its face, that any one compound could have all of those uses. Even if it were, it would require undue experimentation to determine what host – dosage relationship would produce what result. Many of the uses listed are so sensitive that they do not have an established regimen *of* treatment.

J. M. Ford:jmr

October 29, 2003



JOHN M. FORD  
PRIMARY EXAMINER



Gregory A. Smith 1624